P 27/5

NCHSR

program note

NATIONAL CENTER FOR HEALTH SERVICES RESEARCH
AND HEALTH CARE TECHNOLOGY ASSESSMENT
18-12 Parklawn Bldg. • Rockville, MD 20857 • 301/443-4100

Annual Report to Congress on the Patient Outcome Assessment Research Program: Fiscal Years 1987-1988

Pursuant to Section 1875(c) of the Social Security Act, 42 *U.S.C.* Section 1395*ll*(c) as amended by Section 9316(a) of the Omnibus Budget Reconciliation Act of 1986, P.L. 99-509, the National Center for Health Services Research and Health Care Technology Assessment (NCHSR), acting for the Secretary of the Department of Health and Human Services, is authorized to undertake the following mission:

- To establish a patient outcome assessment research program to promote research with respect to patient outcomes of selected medical treatments and surgical procedures for the purpose of assessing their appropriateness, necessity, and effectiveness.

Scope

The scope of the research program includes efforts to provide for:

- Reorganization of data relating to claims under parts A and B of Title XVIII in a manner facilitating patient outcomes research
- Assessments of the appropriateness of admissions and discharges
- Assessments of the extent of professional uncertainty regarding efficacy
- Development of improved methods for measuring patient outcomes
- Evaluation of patient outcomes
- Evaluation of the effects on physicians' practice patterns of the dissemination to physicians and peer review organizations of the findings of the above research

Criteria

In order to determine the priorities for conducting a patient outcome assessment research program, two principal criteria have been specified. Priority will be given to those medical and surgical treatments and procedures for which:

- Data indicate a highly variable pattern of beneficiary utilization in different geographic areas, and which are
- Significant in terms of utilization, length of stay, costs to the research program, and patient risk involved

Funding

No monies were specifically appropriated to NCHSR in fiscal year (FY) 1987 for conduct of the research program. In FY 88, Medicare Trust Fund dollars were transferred from the Health Care Financing Administration (HCFA) to NCHSR in the amount of $1.915 million. Ongoing obligations for FY 89 in the form of continuing support for existing studies amount to $788,215 in direct costs and will increase as a function of new project starts during FY 89. The FY89 appropriation amounts to $5.879 million.

HE 20.6512/6:

Program Note

After consulting on the scope of the program with the Council on Health Care Technology of the Institute of Medicine, NCHSR issued a program note in September 1986 entitled, "NCHSR Solicits Proposals for Research in Medical Practice Variations and Patient Outcomes," advising the research community of the new program and suggesting areas of emphasis for proposals focusing on medical conditions having particular relevance to the Medicare program as follows:

Model evaluations of patient outcomes

Two approaches using current methods and measures are encouraged to explore issues related to frequency of utilization, length of hospital stay, costs, and risk to the patient for medical treatments and surgical procedures whose use varies significantly in different communities:

- Evaluations of the outcome and costs of surgical, medical or diagnostic procedures using available technology assessment methodologies such as literature review, meta-analysis, large insurance claims data bases and assessment of patient's functional status in order to provide better information on the probabilities of given outcomes and the differences in results and costs associated with different practice patterns.

- Examination of the role of clinical data banks in evaluating particular patterns of diagnosis and treatment in specific clinical settings in terms of costs and patient outcomes. Further testing is needed to determine whether the results of such nonexperimental studies are valid for comparisons of effectiveness or costs of different treatments across different institutions.

Admission and treatment criteria

Given the controversy and uncertainty surrounding the appropriateness and value of treatments and procedures as well as the setting in which they are provided, accurate knowledge about the extent and consequences of disagreement in these areas is required. Outcomes research is encouraged in areas such as:

- Empirical validation of the effectiveness of guidelines for reducing practice variation.

- Assessment of evidence supporting conflicting opinions of the processes of practice including the decision process involved in hospital admission.

- Exploration of the relationships between admission criteria and patient outcomes.

Improvements in research methods and data sources

The identification and testing of more complete and accurate data sources, more powerful research study designs, and more efficient analysis techniques are required to relate differences in practice patterns to patient outcomes, including:

- Utilization and integration of the various components of the Medicare claims data system.

- Further development of measures of patient outcome, e.g., functional status and quality of life.

- Better methods for identifying and comparing the costs of treatments and procedures.

- Efficient means of estimating appropriate geographic areas and population characteristics.

- Examination of the factors associated with practice pattern variations and the generalizability of the variations identified.

- Research into unanticipated effects of practice pattern alteration.

- Experimental investigations to resolve incomplete or conflicting results from literature- or claims-based patient outcome studies.

Process

NCHSR utilizes established procedures, based on the NIH model, for the peer review of research grant applications and cooperative agreements directed toward patient outcomes assessment research. In particular, three standing review panels meet triannually to review these applications for scientific and technical merit. Also reviewed are applications addressing a variety of other important health services research issues, such as the impact of AIDS on the costs and use of health services, technology assessment, and home health care. The three panels are the Health Care Technology Study Section, the Health Services Research Review Subcommittee, and the Health Services Developmental Grants Review Subcommittee. Progress is reviewed annually

for noncompeting continuation applications by a combination of staff and Federal or non-Federal consultants, which provide continuity with the original review panel.

Background

Although NCHSR has focused many studies on the quality of health services, research on the effectiveness of medical practice is a priority. The assessment of the effectiveness of health care technologies and new procedures is critieal because their proliferation has provided physicians with many alternative modes of diagnosis and treatment.

Studies, such as those conducted by Wennberg and others, have shown large variations in the use of hospital resources for specific problems, both within and across geographic areas. Variations in the nature of patient outcomes and complication rates after surgery have also been documented. The variations tend to increase with the degree of uncertainty surrounding the criteria for diagnosis or indications for surgery compared with medical treatment. The relationship between these variations and their implications for patient outcomes is not well defined and requires further research. Among the many factors, such as hospital, physician or patient characteristics, that could conceivably account for this variation, physician practice style appears to be the most important. Yet when such factors are carefully controlled, unexplained levels of variation are still evident. This points up the needs for more sophisticated methods for assessing health care outcomes and for improving the clinical decision-making process.

Thirteen Patient Outcomes Studies

The following thirteen studies are being supported by NCHSR with amounts shown for each year of grant funding. They address a range of issues, including methodological development and research into the causes and effects of practice variations in treatment, outcomes, and utilization of resources.

Evaluating Outcomes of Hospital Care Using Claims Data, John Wennberg, principal investigator, Dartmouth College, FY 87: $653,807 (Total Cost); FY 88: $697,687.

This study is evaluating the extent to which insurance claims data can be used to evaluate outcomes associated with surgical procedures and medical admissions to hospitals. In addition to further work on prostatism, the investigators have selected five surgical and two medical procedures for patient outcome assessment. The work on prostatism will also pursue the unexpected finding from an earlier study that the mortality rate following open prostatectomy is less than that for transurethral resection of the prostate (TURP), a procedure that has largely replaced open surgery in the United States.

Variations in Physicians' Practice Style and Outcomes of Care, Sheldon Greenfield, principal investigator, The Rand Corporation, FY 88: $539,389; FY 89: $418,877 (Direct Costs – D.C.); FY 90: $129,366 (D.C.)

This is a collaborative effort involving three private foundations, NCHSR, and NIA. It is designed to address questions of variation in patient outcomes among systems of care when organizational and financial arrangements differ, when case-mix differs, and when the relationship between diagnosis, severity of illness, and functional well-being is taken into account.

National Program to Improve the Quality of ICU Services, William A. Knaus, principal investigator, George Washington University, FY 88: $371,851; FY 89: $250,000 (D.C.); FY 90: $250,000 (D.C.); FY91: $250,000 (D.C.); FY92: $250,000 (D.C.)

This study has set about to improve and develop the severity of illness classification system known as APACHE II as a valid and reliable national performance indicator for intensive care units and as an effective means for improving quality of care and the assessment of appropriate levels of care.

Small Area Analysis of Surgery for Back Pain, John D. Loeser, principal investigator, University of Washington, FY 88: $84,549

This small area analysis of back surgery in the State of Washington was a test of the validity of such analysis in urban areas as a tool in reducing the incidence and costs of the management of lower back pain.

Variation in Third Molar Extraction and Complication Rates, Victor Badner, principal investigator,

Albert Einstein College of Medicine, FY 88: $114,375

Third molar extraction is a high variation dental procedure with significant operative risk. This effort is studying the reasons for the wide variation in the rates of extraction and will lay the ground work for further assess-ment of the personal and social costs of possible excessive third molar extractions and subsequent complications.

Changing Practice Patterns with Comprehensive Feedback, Anthony L. Suchman, principal investigator, University of Rochester, FY 86: $39,161; FY 87: $45,389; FY 88: $0

This study is implementing and evaluating an information feedback program designed to influence physician practice patterns and ultimately hospital costs. The use of an existing hospital data base helps in containing costs and improving quality, and the feedback method developed has the potential for widespread diffusion since many hospitals have similar data bases.

Meta-Analysis for Medicine: Application and Methtods, Frederick Mosteller, principal investigator, Harvard School of Public Health, FY 88: $263,083; FY 89: $119,338 (D.C.); FY 90: $211,300 (D.C.)

This recently begun study will generate the capability to produce high quality assessments of medical procedures through the combining of evidence from many studies and will evaluate the impact of the dissemination of these analyses on the practice ot medicine.

Variations in Coronary Artery Bypass: Determinants and Clinical Significance, Jane L. Halpern, principal investigator, FY 87: $20,000; FY 88: $ 2,000

This is an analyses of small area variations in the performance of coronary artery bypass surgery in the State of Maryland, which is attempting to delineate patient and physician factors contributing to the variations. It also seeks to determine whether practice variations lead to variations in patient outcomes.

Small Area Variation in Connecticut Hospital Discharges, Mark W. Legnini, principal investigator, Yale University, FY 88: $21,600

This is a small area analysis of the variation in the use of hospital services across hospital market areas in the State of Connecticut. By quantifying variation in hospital use by DRG and by market area, it could have potential ramifications for targeted utilization review, reimbursement controls, and continuing medical education.

Practice Variation in Care of Arthritis, Curtis J. Henke, principal investigator, University of California at San Francisco, FY 88: $59, 581

This research will provide greater understanding of the determinants, importance and consequences of differing rates of hospitalization and surgery for rheumatoid arthritis by examining practice variation and individual practice style differences among specialists in rheumatic diseases.

Evaluation of the Outcomes of Prostatectomy, Tavs Andersen, principal investigator, University of Copenhagen, FY 88: $50,000

This study is modeled after research performed in the U.S. by Wennberg and will augment knowledge concerning the outcomes of prostatectomy in a health care delivery system that is different from that in the U.S. while providing an opportunity to compare how different systems deal with the same problem.

Variations in Patterns of Primary Care Among the Elderly, Charlyn Black, principal investigator, The Johns Hopkins University, FY88: $21,316

This study is a retrospective analysis of existing research data on the elderly derived from claims data from the Province of Manitoba insurance program and claims related survey responses from the Manitoba Longitudinal Study on Aging. It seeks to assess important attributes of primary care, i.e., first contact care, comprehensiveness, coordination, and longitudinality by examining the degree to which age, sex, health status, education, and monthly income explain variation in practice patterns.

Inappropriateness and Variations in Hospital Use, Michael Schwartz, principal investigator, Boston University, FY 88: $294,532

> To study the relationship between high hospitalization rates and inappropriate hospital use, longitudinal data for Medicare patients over a 5-year period in each of 45 hospital service areas in Massachusetts will be analyzed by year and condition to determine discharge rates and their relationship to the appropriateness of care. It is hypothesized that for diagnostic conditions with larger between-area variability in hospital rates, the rate of inappropriateness will be higher in areas with high hospitalization rates and lower in areas with low hospitalization rates. This work will provide the foundation for a larger research effort aimed at increased understanding of the interpretation of data on small area variations in the use of hospital resources. It focuses, therefore, on definitional and methodological development.

Future Directions and Coordination of Efforts

These grants reflect the Center's start on a number of methodological issues to develop better ways to carry out patient outcome studies, while at the same time looking at some major issues arising from variations in treatments, outcomes, and resource consumption. Using this as a base, NCHSR will expand the Patient Outcome Assessment Research Program (POARP) with emphasis on six areas:

- Assessments of the appropriateness of admissions and discharges;
- Assessments of the extent of professional uncertainty concerning treatment effectiveness;
- Development of improved methods for measuring patient outcomes;
- Evaluation of patient outcomes;
- Evaluation of the extent to which dissemination of the findings of this research to physicians and peer review organizations can affect physicians' practice patterns; and, finally,
- Working with HCFA on reorganization of Medicare data files relating to claims under Parts A and B to facilitate patient outcome research.

To extend this program in FY 89, NCHSR's POARP will initiate support for four Assessment Teams as a means to identify and analyze the outcomes and the costs of alternative practice patterns. This will serve as a basis for developing and testing feasible and acceptable methods for reducing inappropriate variations. Ultimately, this will lead to the development of patient outcome information for physician decision making that will improve quality of care.

HCFA is collaborating with NCHSR on two of NCHSR's patient outcome research grants. In FY 88, HCFA transferred funds to NCHSR to provide joint support to Dr. John Wennberg of Dartmouth University. Through this grant, Dartmouth and the Maine Medical Assessment Program are working together on a project to determine the utility of insurance claims data in evaluating patient outcomes associated with surgical procedures and medical admissions to hospitals. In addition, NCHSR and HCFA are collaborating on studies to refine a severity classification scheme to aid in evaluating the appropriate use of intensive care units.

NCHSR and HCFA will continue to work in concert to avoid duplication and overlap in the expansion of these research activities as part of the proposed Medical Treatment Effectiveness Research Program. NCHSR's criteria to be used for selecting the illness/medical treatment topic areas to be studied through POARP were developed in cooperation with other agencies, including HCFA, and in consultation with the Institute of Medicine's Council on Health Care Technology and members of the practicing and research community.

HCFA is in the unique position of developing, linking, and enhancing its clinical and claims-based data on the entire Medicare population, over 30 million people, in order to better understand the relationship of specific services and courses of treatment to medical outcomes. NCHSR looks to HCFA for the development and enhancement of Medicare data so that these data will reveal variations in the treatment/conditions of aged patients, provide guidance for areas/topics in need of assessment, and facilitate patient outcomes research.

As part of the Medical Treatment Effectiveness Research Program, NCHSR assessment teams will add to HCFA's findings by supplementing Part A and Part B claims with information from medical records and clinical trials. The purpose is to determine what additional patient characteristics not in Medicare files influence the physician's choice of treatments and the patient outcomes that we see. Further, NCHSR's research in the development of health status, functional status, and severity of illness measures will eventually be built into the Medicare (and, hopefully, the Medicaid) data bases.

Our approach to the assessment of patient outcomes includes the following activities:

1. Multidisciplinary Assessment Teams which include practicing physicians;

2. Other investigator-initiated assessments;

3. Experimental trials as required;

4. Data source development and maintenance;

5. Training of research manpower; and

6. Demonstrations of the effectiveness of the research products.

Dissemination of Research Results

As patient outcome effectiveness research is completed, the results will be widely disseminated. An explicit part of the structure of the patient outcome research program of NCHSR is the inclusion of practicing physicians on the assessment teams. This approach, employed experimentally in Maine, has demonstrated that research findings relating to appropriate treatment become common practice in a very short time. NCHSR will also assist the diffusion of the information derived from its assessments by publishing results in a series of technical reports similar to those now issued under NCHSR's *Health Care Technology Assessment Report* series.

With respect to the dissemination of information on appropriate diagnostic and therapeutic procedures for those over 65 years of age, HCFA is critically important. Through various administrative mechanisms, HCFA is in a unique position to share information on the effectiveness of medical practice with practicing physicians.

The research results from both will be transferred to the Health Resources and Services Administration (HRSA) to assure that the findings become integrated into medical education. One important audience for the findings of patient outcome research is medical school faculty responsible for training new physicians and providing continuing education. They are in a position to influence both the way new physicians think about and evaluate what they do and to transfer information on the scientifically demonstrated appropriate way of handling particular problems. The responsibility for developing teaching materials, transferring findings from research, and influencing curricula development will rest with HRSA.

Confidentiality of patient data, collected or acquired in the course of the research grant process, is protected under section 474(a) of the Public Health Service Act implemented by HHS regulation 45 *CFR* 46. All such research must be reviewed and approved by an institutional review board (IRB) as well as by reviewers acting on behalf of the grantor. This process is discussed in detail in the PHS Grants Policy Statement (1987) and, in general, provides for minimization of risks to patients,guarantees of informed consent, protection of the privacy of subjects, and the maintenance of confidentiality of data. Grantees are required to provide written Assurances of Compliance with 45CFR 46 and to file a certification that the proposed research activity has been reviewed and approved by an IRB in compliance with the regulation. A memorandum of understanding between HCFA and NCHSR regarding the use of Medicare and Medicaid data for research purposes has been drafted and is awaiting final approval.

In FY 90, results from some of the initial grants awarded by NCHSR in FY 88 under POARP will become available. These results will provide NCHSR, HCFA, and HRSA with a set of information to disseminate to the medical and research communities. It is anticipated that the methodological work being developed through these initial POARP grants will help physicians and health care providers to collect information differently.

Patient outcome research has had significance for saving lives, improving the quality of medical care, increasing and maintaining functional abilities of patients, conserving resources, and reducing frivolous malpractice suits.

This can occur as a result of resources devoted to developing and disseminating better scientific knowledge about patient outcomes, thus allowing physicians and their patients to make better informed decisions about treatment choices.

DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
National Center for Health Services Research
and Health Care Technology Assessment
Parklawn Building, Room 18-12
Rockville MD 20857